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Developing a Wearable Medical Monitoring Device

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Abstract

As Covid-19 spreads around the world, and hospitals become overwhelmed, the use of cost-effective remote patient monitoring systems becomes more relevant than ever. To combat the pandemic, these solutions provide real-time data on the vital signs of patients, enabling the monitoring of an order of magnitude more patients, while reducing the risk of infections.

This thesis explores the development of a wearable medical monitoring device with a focus on the design process of the case and the sensor enclosures. The secondary goal of the thesis is to investigate the additive manufacturing processes currently viable for small companies, evaluate and compare them, and present their use cases relevant to prototyping and manufacturing wearable devices.

First, the thesis lays down the theoretical foundation for the design process, including the design guidelines and the technologies used in the device. It also presents the technical details of the most common additive manufacturing processes. Subsequently, the design process and decisions are discussed, followed by the design solutions of the final device, in conjunction with its accessories.

This is followed by a section exploring the peculiarities of different additive manufacturing processes and their use cases in prototyping and manufacturing parts for a monitoring device.

Finally, the thesis shares the results of validation tests and concludes the thesis with a summary and possible improvements for the future.

Keywords Medical Monitoring, Wearable Technology, Additive Manufacturing, 3D Printing

Contents

Preface

I want to thank Professor Petri Vuorimaa and my advisor Miklós Knébel for their help and guidance.
I also want to thank everyone at Entremo for making this thesis possible and supporting me while I was busy working on it.

Budapest, 30 July 2021
Péter Dános

Abbreviations

CAD	Computer Aided Design
ECG	Electrocardiography
FDM	Fused Deposition modelling
FFF	Fused Filament Fabrication
ICU	Intensive Care Unit
Laser	Light Amplification by Stimulated Emission of Radiation
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MSLA	Masked Stereolithography Apparatus
PCB	Printed Circuit Board
PET	Polyethylene Terephthalate
PETG	Polyethylene Terephthalate Glycol-modified
PLA	Polylactic Acid
PP	Polypropylene
PPG	Photoplethysmography
PS	Polystyrene
PVA	Polyvinyl Alcohol
RGB	Red, Green, Blue
SLA	Stereolithography Apparatus
SLS	Selective Laser Sintering
TPE	Thermoplastic Elastomer
UV	Ultraviolet

1 Introduction

1.1 Background of research problem

Currently, at hospitals only a small fraction of patients are actively monitored at all times. The vast majority of patients do not need constant monitoring, and current solutions for remote monitoring are expensive[1] and complicated to use. For this reason, it is mostly done in Intensive Care Units (ICU)s, where specialized equipment and trained staff is available for this task. However, with the rise of cheap non-invasive monitoring sensors, and advances in IoT technology, it became possible to develop more cost-effective monitoring devices. While these are not as feature complete as ICU equipment, they can provide a viable solution for the group of patients that would benefit from continuous monitoring but are not in a critical condition.

There are existing solutions for this problem, such as Biosensor BX100 by Phillips [2], the Chest Monitor by Biobeat [3], or the Oxitone 1000M by Oxitone [4]. However, there is still a need for a solution that is reusable, cost effective, easy to use, and specifically designed to monitor patients with respiratory symptoms.

This thesis investigates the design considerations and processes of developing a wearable medical monitoring device with a focus on the enclosure of the device and the encapsulation of its sensors. The thesis also explores the state of additive manufacturing technologies and their use in a start-up setting.

1.2 Motivation

Respiratory diseases, such as Covid-19 exponentially increase the number of patients in need of continuous monitoring at hospitals. Due to their very limited ICU capacity, hospitals are not well equipped for situations like this, and expanding their ICU capacity is not a viable solution due to its cost and the need for trained nurses and medical personnel [5]. According to my interviews with several doctors, nurses and healthcare professionals at Hungarian hospitals, the current method for monitoring Covid-19 patients not in intensive care was done manually. 3 times a day nurses measure the vital parameters of patients using traditional medical measurement devices and log the results using pen and paper.

We had identified two main problems with the current state of Covid-19 patient monitoring, which we aimed to create the solution to. The first was the time consuming and resource intensive process of manual patient monitoring. Solving this problem would free up hospital staff to be able to tend to patients most in need of assistance. It would also reduce the

probability of infections from patient to nurse, and across patients. The second problem is the low frequency of the manual measurements. This means that if a patient's health deteriorates between measurements, for example at night, doctors could only intervene later, and the consequences could be more severe.

1.3 Objectives and scope

The primary objective of this thesis is to lay down a foundation of knowledge about how to design a wearable medical monitoring device. I aim to uncover what the main factors involved are, and how to make the right design decisions that will lead to a functional device. This is done by dissecting and analysing the design process, and by discussing the reasons behind the design solutions on the final device.

The second objective of this thesis is to answer the following theoretical question by research and hands-on experience in the industry:
How can additive manufacturing processes be used for prototyping and small-scale manufacturing at a start-up?

The goal is to gain a deeper understanding of the 3D printing processes and their applications for certain use cases. I will be comparing these processes in detail, including their costs, usability, potential use cases and limitations. With my thesis, my goal is to provide research and experience-based insight into the process of choosing the right additive manufacturing process for the right use case.

The scope of my work discussed in this thesis is mainly the designing, prototyping and manufacturing of the enclosure of the monitoring device and its accessories. This includes the form factor and detailed design of the case of the device, the sensor encapsulations and the assembly. It also includes the operation of several 3D printers for prototyping and manufacturing.

In this thesis, I am writing about my own work, and the work of the company in general. As Entremo [6], the company I did my thesis work at, is a small start-up, I was involved in almost all the major general decisions on how the system should be engineered. However, because some of these design problems and decisions are discussed in length, I would like to clarify in advance, that parts written in the first-person plural form are all common decisions of the team and not exclusively my own work. On the other hand, the rest of the thesis, written in the first-person singular form, is my individual work exclusively.

1.4 Overview

The thesis consists of four main sections, a theoretical background of designing a medical monitoring device and additive manufacturing, an

explanation of the design process, a demonstration of additive manufacturing use cases, and finally, the results and conclusion.

In the first section, the thesis lays down the theoretical foundation for the design process. It introduces the design guidelines and the technologies used in the device. It also presents the technical details of the different additive manufacturing processes discussed in the thesis.

The second and section of the thesis present the design process and decisions as well as the reasons behind them. It also showcases the completed device and explains the design choices, including the encapsulations of the sensors. The wireless hub case and charger for the devices are also discussed in this section.

The secondary goal of the thesis is realized in the third section, which is about the details of the different additive manufacturing processes and their use cases. The section details the benefits and limitations of different additive manufacturing processes and compares their properties and possible uses.
Finally, the last section of the thesis shares the results of validation tests and concludes the thesis with a summary and possible improvements for the future.

2 Theoretical background

2.1 Theoretical background of design

2.1.1 Design questions

The first and one of the most crucial steps in designing a wearable medical monitoring device is to clearly define the use case and the use environment of the product. This should be based on research, questionnaires and interviews. A good engineering solution should always be based on a thorough requirement analysis, and especially if the developers are not overly familiar with the environment it will be used in. A good way of doing such research is by forming questions and finding the answer to those:

What is the purpose of the device?
While this might seem like an obvious question, it is essential to determine the exact function of the device. It can be a non-invasive measurement tool, or it could also intervene in some way, for example administering medicine. If its purpose is to remotely monitor patients, the measurements taken, the frequency of the measurements and their required accuracy all have to be established.

Who will be wearing the device?
Everyone is different, and this is especially true for hospital patients. Once the purpose of the device is established, the group of patients who could benefit from its use can be determined. If only conscious patients would be wearing the device, a certain amount of active interaction can be acceptable, however, it also depends on the age of the patients, and whether they would be able to interact with the device [7]. On the other hand, if the device has to take measurements while the patients are asleep, the whole process must be automatic. Another important factor is whether the patients are bed-bound, or are able to move around freely, as this influences the design possibilities regarding ergonomics and connectivity.

In what environment and by whom will the device be operated?
Hospitals vary greatly, and one cannot expect them to have the same infrastructure or capabilities. Therefore, it is vital to survey what can generally be expected in locations where the device would be used. The staff working there and the people who would operate the device are also crucial factors. We must know what skills or abilities they have or what technical training would be necessary for them to be able to handle the devices. It is also important to know how they could integrate such a remote monitoring solution into their workflow.

Will it be reusable, or does it have to be discarded after a single use?

While discarding the complete device after a single use might seem wasteful and unsustainable, there are cases where it is a good solution. If the device can be cheaply produced, has consumable parts or there is no good solution for recharging its battery, disposability can be a viable option. It makes the workflow with the device simpler, as it does not require charging or any sort of maintenance between uses. It also removes the risk of infection from one patient to another or to a hospital worker. On the other hand, a reusable device is more sustainable and cost-effective in the long term. Higher grade sensors and other components can be used, which could provide more accuracy and reliability.

How and where should it be attached to the body?

There are generally two methods on how a device can be attached, either with an adhesive, or a strap. The method to choose highly depends on where it should be placed on the body which in turn depends on the vital signs measured and the sensors used. ECG sensors, for example, are best placed on the chest, which makes an adhesive attachment a favorable option, while a blood pressure sensor is best used on the arm, where a strap is the better solution [8].

Some sensors, like a reflective PGG, can be placed on many different places on the body, however, they all vary in the strength of the signal and thus the accuracy that can be attained. Comfort and other usability factors also must be taken into consideration when deciding where on the body the device should be placed. When multiple parameters are measured it is crucial to find the optimal location, where all are adequately accurate and can function reliably. Placing a sensor in a suboptimal location can also be advantageous, if the benefits of the location, like ergonomics or usability, outweigh the reduced signal strength. However, in these cases, the development of the sensor and signal processing are more complicated, time-consuming and expensive.

Should it be connected wirelessly, or by a wire?

If the use case allows it, for example, if the device is only used by bed-bound patients, having the device physically connected to an electric source and the network at all times can be advantageous. There is no need for a battery, and there are no difficulties with the complexity and reliability of a wireless network. On the other hand, it severely limits the potential use cases, requires a robust network infrastructure as well as validated electrical shock protection. It is also questionable whether a device can be called wearable if it must be physically connected at all times, thus it is somewhat outside the scope of this thesis.

What infrastructure is required to operate the monitoring system, and how can it be deployed?

A wearable device cannot operate as a medical monitoring system by itself. It needs electrical power, a network connection, and a system for viewing the measured data.

This system can be integrated into the existing patient monitoring infrastructure of the hospital, or it can be an entirely self-contained solution. Either way, the system should only be reliant on the minimum infrastructure that is available at each site where the devices could be deployed. This stage of planning is crucial, as this will determine the possible deployment sites, the ease, speed and cost of each deployment. Integrating with the existing system of the hospital leads to improved usability and workflow, however, increases the complexity of the development, testing and each deployment.

How long should it last on a single charge?

As almost every other design consideration, this is highly dependent on the use case. How long does a single patient in need of monitoring spend in the hospital? How often can the nurses charge the device without it disrupting their workflow? How often do measurements have to be taken? How much power does the device draw? What space and weight limitations are there for the given form factor? Optimizing the power consumption and choosing a battery suitable for the task is a balancing act and depends on the answers to all the aforementioned questions [7]. A general goal can be set at the beginning of the design process; however, the end result is likely to change one way or another during the development process.

What wireless communications standard to use?

There is a multitude of wireless communication standards that can be used in a wireless medical monitoring device. There are two main ways the devices can connect to the server, either directly through the internet via a mobile network, or by connecting locally to a gateway which then enables communication with the server. For the first option, the Narrowband IoT protocol can be used, which is a mobile network specifically designed for energy efficiency and low cost. For a local network, there are several options, the widely used Wi-Fi and Bluetooth, or LoRa, which is a long-range wireless communication standard [9]. The wireless protocol should be chosen with the consideration of several aspects. What are the range requirements from the device? How many devices should a single gateway be able to handle? How complicated is the implementation of the chosen protocol? How much power does it use on the device? Only by thoroughly analyzing all these factors can we design a solution, which is right for the given use case.

Which materials to use?
For a wearable device, which will be in contact with human skin, selecting the proper materials for the case of the device is crucial. They must not cause irritation or allergic reactions, or in other words, all materials that come in contact with any part of the body must be biocompatible. This applies to the case of the device, the adhesive used, the sensors and the strap.

What would be a typical use process?
The use process can be designed based on the previously defined use cases. It covers what happens with the device and the monitoring system in general from the point of deployment. This should at least cover the following:

- How the device is activated and connected to the system
- How it is assigned to a patient
- How it is put on the patient
- How the measurements are viewed and documented
- What interaction and maintenance it requires during its usage on the patient
- How it behaves through the daily activities of the patient
- How it can be taken off the patient
- The charging or disposal process
- Disinfection and maintenance between different patients
- How the patient is tracked between different devices

2.1.2 Encapsulation of a PPG Sensor

Photoplethysmography is a non-invasive, optical method of detecting blood volume changes, heart rate or blood oxygen saturation [10]. As blood is pumped by the heart it travels through the body in the arteries and is carried to the skin, where a sensor can be placed. Because the absorption coefficient of blood is known, it can be used to detect changes in the absorption, as the blood is pumped in cycles by the heart [11]. As the heart beats, it produces blood volume changes in the skin tissue, and this can be detected by emitting light through the tissue and detecting the light with a photodiode. Most of the light is absorbed by different tissues of the body and only some of it is absorbed by the blood. However, because of the pulsating nature of the blood, by processing the signal, the pulsatile component can be isolated, and used for measuring vital signs [11]. From this pulsatile component, the heart rate can be measured by calculating the frequency of the pulses.

There are two possible physical sensor configurations, depending on the region of the body the sensor is placed at [12].
Transmissive PPG sensors work by shining light through a thin part of the body, like fingers, or the earlobe. The light passes through the body and is

measured on the other side. This is how the widely used finger-based pulse oximeters work. [11]

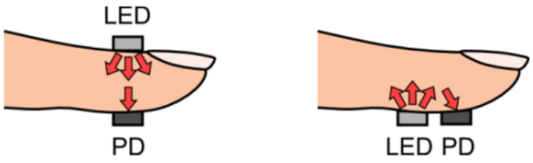

Figure 1: The component placement of transmissive and reflective PGG sensors [13]

On regions of the body, where light would not be able to penetrate through the body, **reflective** PPG sensors can be used instead. In these sensors, the light source and the photodetector are placed on the same side of the body, next to each other. The principle of operation of these sensors is that the part of light not absorbed is reflected to the sensor, and by isolating the pulsatile component, the same measurements can be achieved. [11]

PPG for pulse oximetry

SpO2 is the measure of peripheral capillary blood oxygen saturation, and it is a non-invasive alternative to arterial blood oxygen saturation, SaO2. To measure the percentage of oxygenated blood, pulse oximetry exploits the difference between the absorption coefficient of oxygenated and non-oxygenated hemoglobin, the molecules responsible for carrying oxygen in the blood. Using two different wavelengths of light, red and infrared, the difference in absorption between the two light sources is used to calculate the blood oxygen saturation. [14]

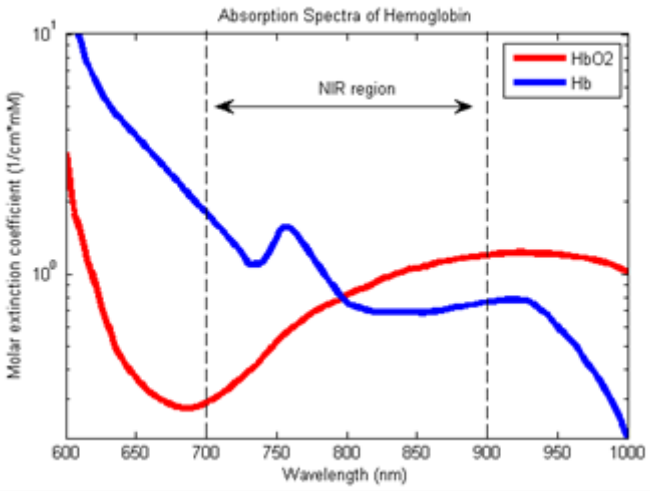

Figure 2: The absorption spectra of hemoglobin [15]

There are two main components to every PPG sensor, the LEDs and the photodiode. For measuring heart rate, the optimal wavelength for the light source is around 550 nm, as the absorption coefficient of blood is highest at that wavelength. However, due to the manufacturing limitations of green LEDs, a light source of around 530 nm is used instead. [16]

For pulse oximetry, a red and an infrared LED are needed at 660 nm and 940 nm wavelengths respectively. Choosing light sources with a narrow beam angle is preferred, as it minimizes crosstalk and improves the signal to noise ratio. [14] The Photodiode should be chosen such that it has high responsivity to the wavelengths emitted by the LEDs [17].

As the sensor is in direct contact with the skin, there has to be some sort of barrier between them. It provides a water barrier and helps the sensor to be fixed in relation to the skin surface. The most important physical property of the encapsulation is its opacity. The material must be optically transparent at all the visible and infrared wavelengths the sensor uses. Furthermore, the refraction index of the material should be close to that of the human skin to minimize Fresnel reflection induced transmission losses. Finally, the material should be skin-safe, and should not induce skin irritation.

There are many different options for the encapsulation material, including glass, rigid polymers and silicones. The right material for a given sensor encapsulation implementation highly depends on the design and manufacturing constraints. The encapsulation should be designed to minimize the distance of the sensor to the skin and the thickness of the encapsulating medium itself. [16, 17]

2.1.3 Encapsulation of the Temperature Sensor

There are many forms of temperature sensors, ranging from simple thermistors to infrared thermometers. In this section, I will focus on how PCB-mounted contact temperature sensors should be implemented in a wearable device.

To get the most accurate measurements, the surface of the temperature should be in direct contact with the skin, however, this is rarely feasible due to design constraints and waterproofing concerns. To make the sensor usable in a wearable design some sort of thermally conductive encapsulation is necessary. To create a good thermal interface, the following design guidelines should be taken into consideration. [20]

A good thermal contact

To have an accurate measurement, it is crucial to have a good thermal contact with the skin at all times. To achieve this, the thermal contact area of the thermal interface should be maximized within the design restrictions. Furthermore, the geometry of the thermal interface should be such that it

creates a secure contact with the device, for instance by protruding from the device slightly. [21], [22]

Selecting the right material for the thermal interface
To minimize the time needed for the measurements to react to a change in the skin temperature and maximize the accuracy, the material used for the thermal interface should have a high thermal conductivity. At the same time, it should also be skin safe, or be covered with a layer of skin safe coating.

Appropriate geometry
When designing the thermal interface part, the thermal mass should be minimized, to increase responsivity and accuracy. To achieve this the thickness of the material should be decreased while still being structurally sound and having a large enough contact area with the skin. [22]

2.2 Theoretical background of additive manufacturing

Additive manufacturing, also known as 3D printing, is an umbrella term used to describe a class of manufacturing processes, where the material is added layer-by-layer producing the desired object. It is very commonly used while prototyping or manufacturing customized parts and objects. The main material used is usually some sort of polymer, however certain technologies can also print with certain metals or ceramics or even concrete. However, for the scope of this thesis, only plastic 3D printing is relevant, therefore, I only write about these processes in detail.

The basic concepts of all three technologies are very similar. The model is created using 3D modelling or CAD software and then exported as a triangle mesh. The next step in the process is to use a so-called slicer software to divide up the model into vertical 2D slices and generate the toolpath. The sliced file can then be sent to the 3D printer which manufactures the model by realizing a single layer at a time. However, the similarities end here, as each process works vastly differently, requiring distinct preparation and post processing steps.

2.2.1 Fused Filament Fabrication

Fused Filament Fabrication (FFF) or more commonly known as Fused Deposition Modelling (FDM) is the most common additive manufacturing technology, widely used to create prototypes quickly [23]. It uses a plastic filament that can be made from PLA, PETG, ABS or a range of other materials.

The printer consists of a 3-axis movement system, a build platform, a heated nozzle, and an extruder. The process works by pushing the plastic filament through a heated nozzle, which melts it. The molten plastic is then

deposited in a predetermined path a single layer at a time, using the machine's 3-axis movement system. Upon leaving the nozzle, the plastic quickly hardens, retaining its shape, which is helped by a cooling fan. After completing a layer, either the nozzle moves up, or the build platform lowers by a certain distance, leaving just enough space for the printhead to build the next layer on top of the already printed part. After the printing is done, the part can simply be removed from the bed and, in most cases, does not require additional post-processing steps. [23]

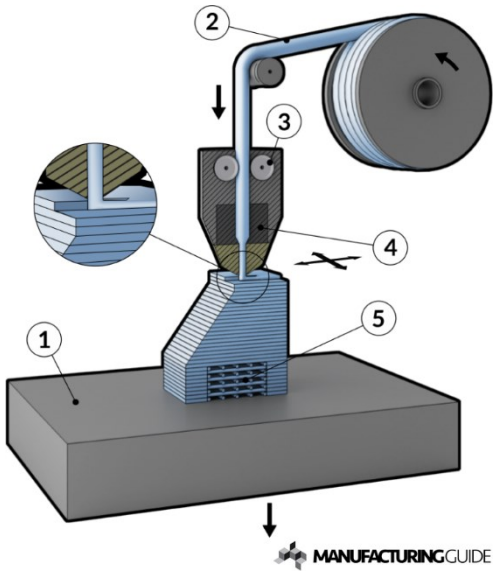

Figure 3: How the FFF process works [24]

A limitation of FFF 3D printing is that the nozzle cannot deposit molten plastic mid-air, so when the geometry of the printed object requires it, a support structure has to be built underneath the overhanging part. This can be printed from the same material with a very small gap, and then removed once the print is finished. Printers capable of printing more than one material at a time can also use a different plastic for the support structure. In this case a water-soluble plastic, for example PVA, can be used, and simply washed away after printing.

One of the main advantages of FFF 3D printing is its low cost: machines and consumables can be purchased for a low price compared to the other two processes described in this paper. Easy pre- and post-processing and a relatively short printing time also make it a favorable option for rapid prototyping and iterative design.

On the other hand, FFF lacks the precision and resolution that other processes can offer, and as mentioned, is limited by the geometry of the printed part.

2.2.2 Masked Stereolithography

Stereolithography, or SLA is one of the oldest additive manufacturing processes. It creates parts by selectively polymerizing a photopolymer resin using a light source, usually an ultraviolet laser. There are two different ways SLA printers are built, but in both cases, the resin is kept in a vat. The laser can be directed using a pair of mirrors individually controlled by two motors, tracing out a single layer at a time, in a path calculated by the slicer software.

In top-down machines, the build plate is submerged in the resin, while the laser is mounted above the vat. The first layer is printed on top of the build plate, and with each layer, the plate is lowered deeper into the vat. When the process is done, the build plate rises to the top, revealing the printed part, which can then be removed for post-processing. In the case of bottom-up printers, the vat has a transparent bottom, usually some sort of flexible polymer sheet. The laser is under the vat behind a layer of glass, and the build plate is suspended above the vat. At the start of printing, the build plate is lowered into the vat, leaving only a single layer of resin between it and the bottom of the vat. The laser then selectively cures the first layer, which sticks to the bottom of the build platform. Between layers, the build plate is raised leaving space for the resin to fill the next layer. When the process has finished, the printed part is hanging from the build plate upside down, above the vat. [25]

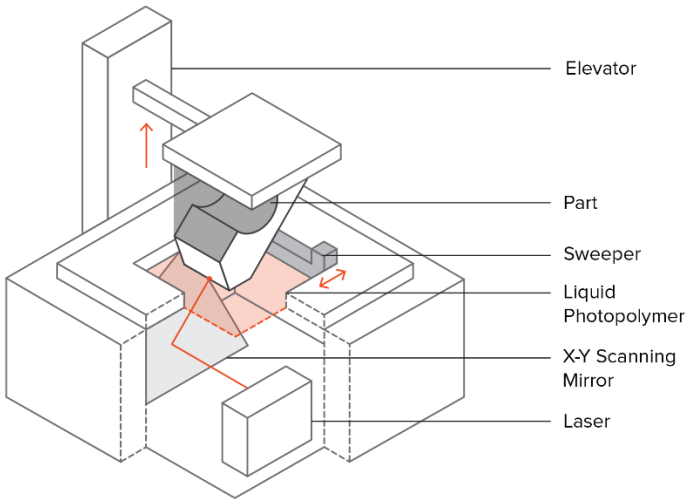

Figure 4: The schematics of an SLA printer [26]

Masked stereolithography or MSLA is a newer, more cost-effective variant of the traditional SLA process. The main difference is that instead of the laser and galvo, UV LEDs and an LCD mask are used to deliver the light in the shape of the printed layer. These machines are exclusively bottom-up, with the LCD mask placed just under the vat. The size and resolution of the LCD

determine the resolution and horizontal accuracy of the machine. Since the LCD is made up of pixels, the printed parts can have visible aliasing when compared to traditional SLA prints. This can be reduced with the use of higher pixel density LCD masks and anti-aliasing. [27]

After the machine has completed the print, it needs to be post processed before it can be used. This consists of two steps, washing and post-curing. As the photopolymer is a viscous liquid, it creates a thin layer of uncured resin on the printed part. This obscures the details and needs to be thoroughly washed away using isopropyl alcohol, or a chemically similar solvent. Finally, the clean part must undergo further curing, which happens under UV light. This solidifies the part and enhances its mechanical properties.

When preparing 3D models for bottom-up SLA or MSLA printing, the object has to be oriented in a way that reduces its per-layer cross sectional area. This is done to minimize the dimensional inaccuracy and print failures due to the suction forces when separating the part from the bottom of the vat at each layer change. In order to achieve this, a considerable amount of support structures is required, which are time consuming to add in the slicer software and then to remove from the part after it has been printed. It also leaves marks on the surface of the print, making it less aesthetically pleasing.

The main benefit of the MSLA printing process when compared to FFF is the ability to resolve details better and the superior surface finish. It is also capable of printing optically clear parts, which is very challenging with a filament-based printer.

However, there are also considerable drawbacks to this technology. Parts printed using SLA are generally weaker and more brittle than FFF parts. In my experience they are also prone to smaller pieces chipping off and tolerate friction very poorly. Furthermore, besides the aforementioned lengthy pre and post processing steps, there are safety and usability concerns when it comes to resin printing. The resin is toxic and must be handled in personal protective gear, consisting of nitrile gloves, safety glasses and a respirator. While printing, the curing process also emits toxic fumes, therefore proper ventilation is crucial. Resetting the machine after a failed print, changing resin, and maintenance are also challenging and time consuming due to the toxic and viscous nature of the resin.

The cost of entry-level MSLA and FFF machines are similar, and the cost of resin and filament are comparable, however running a resin-based machine is considerably more expensive, as it requires a number of costly consumables to operate and maintain. These include nitrile gloves, filters, paper towels, vat bottom sheets, LCDs, amongst others, which all add up to a significantly higher operating cost compared to FFF.

2.2.3 Selective Laser Sintering

Selective Laser Sintering (SLS) is an additive manufacturing process that creates parts from a polymer powder. This polymer is most commonly a polyamide, also known by its commercial name, Nylon. There are many nylon blends and composites used, however, the process also works with TPE, PP or PS powders.

The machine has a build chamber, which heats just below the sintering temperature of the powder, and a powerful directed laser is used to selectively fuse the powder. At the start of the printing process, the build platform is covered with a thin layer of polymer powder, with the help of a roller. The laser fuses the powder, then the build plate is lowered, and the next layer of powder is deposited on top. This process continues until the parts are completed, then the build chamber slowly cools down to minimize the uneven shrinkage of the part due to thermal contraction. After this, the build chamber is removed, with the parts encased in unsintered powder. The parts are taken out from the powder, and excess powder is removed using a brush or pressurized air. The unsintered powder then has to be mixed with virgin powder and used again. [28]

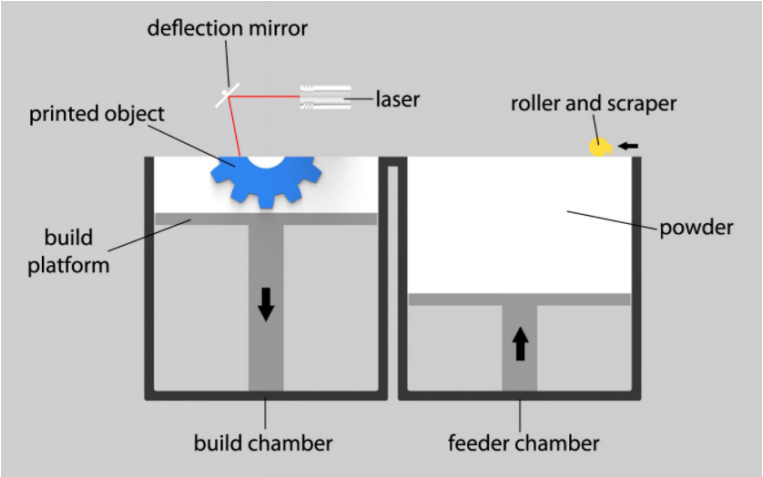

Figure 5: The schematics of an SLS printer [29]

There are many ways the parts can be post processed, including sand blasting and chemical vapor smoothing. These improve surface finish and reduce surface porosity, producing a look and feel close to injection molded parts. [30]

One of the main advantages of SLS printing is that it does not require support structures to be built as the unsintered powder keeps the parts suspended. The process can also clear very small tolerances and clearances, enabling the possibility to print joint moving parts in one piece. These enhance design freedom, solving most of the geometry limitation problems of the FFF and SLA printing processes. The parts produced are also very

strong compared to printing from a similar material with an FFF machine, and due to the nature of sintering, have isotropic mechanical properties, meaning that the mechanical properties are not dependent on the direction of the print process. If the parts are printed from white polyamide, it is possible to dye them after the printing, making coloring the part cheap and accessible.

While all these properties can make SLS a superior option to the other two additive manufacturing processes presented, there are several drawbacks that limit the accessibility of the technology. As the build chamber is cooled down, the printed parts shrink due to thermal contraction. The problem with this is that the shrinkage is not uniform, the horizontal and vertical changes in the size of the parts are not equal. While this can be accounted for during the slicing process, it could still cause problems and requires calibration.

While most SLS printers are heavy, very expensive industrial machines, over the past few years several companies have brought more affordable, desktop models to the market. These are at least an order of magnitude cheaper than their industrial counterparts; they still are not as affordable as desktop FFF or SLA machines. Running these machines also requires additional equipment, such as finishing stations, powder mixing stations, sandblasters, etc. The plastic powder used by the machine is comparable in price to higher end FFF filament or SLA resin, but as stated before, not all unsintered powder can be reused. This problem is twofold: firstly, as SLS machines have to fill the entire horizontal area of the build chamber to operate, a considerable amount of powder becomes deteriorated by the heating of the chamber. Secondly, the ratio of used powder to virgin powder determines the surface quality of the machine. The more used powder there is in the mix, the worse the print quality becomes.

These factors all contribute to the fact that use cases for an SLS machine are a lot more limited. Operating such a machine is only financially viable, if the user can fill up the build chamber with parts, minimizing the unsintered resin wasted in the process. Post-processing and working with the powder, in general, is also very challenging in a home or office environment due to the nature of the fine plastic particles, however, a suitable environment can be constructed and maintained in an industrial setting.

3 Designing the device

3.1 The first prototype

The very first idea of the medical monitoring device was in a glasses-like form factor that would sit on the patients' nose and ears. The main idea behind this design was that patients would already be familiar with the shape and how to use a device like this. It also provided access to certain parts of the body, where vital sign measurements could be taken.

The parameters to be measured for coronavirus patients were established very early on, by consulting with doctors, nurses and healthcare professionals, some of whom were working on the front line in the fight against Covid-19. In most cases these are the vital signs that doctors and nurses already measured and logged regularly for coronavirus patients.

The 3 most important of these parameters are blood oxygen saturation, respiratory rate, and body temperature, therefore our team chose to create a device that can measure these parameters. For measuring body temperature, an infrared temperature sensor was used, which was placed in front of the forehead for accurate measurements. The blood oxygen saturation was measured using a reflective SpO2 sensor module. This was placed on the side of the device, where the patient would put their finger for the duration of the measurement. For monitoring the respiratory rate, we placed a microphone a movable shroud that could be adjusted to be under the patient's nose.

Figure 6: The first prototype

The sensors were connected to an Arduino micro, which could be connected to a computer using a USB cable. The measured values could then be seen using a simple program. For feedback, the device was equipped with an LED strip at the front.

While the prototype worked as a proof of concept, it had many flaws which were uncovered upon further research and interviews with healthcare professionals.

1. Ergonomics
   The first of these drawbacks were the comfort and usability issues regarding the design of the device. A glass frame-like design would be hard to optimize for different head sizes and could prove to be uncomfortable while wearing for multiple days. Sleeping with the device on could be unpleasant thus incentivizing the patient remove it. Therefore, we found this form factor to be unsatisfactory, and discarded its use for later designs.

2. Patient interaction
   This version of the device requires the patient to interact with it periodically to acquire the blood oxygen saturation measurement. This makes the device unsuitable for 24-hour monitoring or use with patients who are not in a state to be able to operate the device.

3. Respiratory rate measurement
   Using a microphone under the nose is not suitable for measuring respiration rate, as it is not able to detect breathing through the mouth. Furthermore, it cannot be used with patients who are being assisted in breathing in any way.

In conclusion, this prototype was successful in proving the feasibility of the idea, and the team learnt a great deal about the challenges of creating a wearable device. The advice we got from doctors and healthcare professionals during the development of the prototype proved to be invaluable during the later stages of the development.

3.2 Design considerations based on the guidelines

After summarizing what we had learnt from the first prototype, a more detailed and deeper research and design phase followed. In this section, I will be going over the design questions I have raised in the theoretical background section and discuss the design decisions we have made as well as the reasons behind them.

What is the purpose of the device?
Based on interviews with doctors, nurses and healthcare professionals, we set out to solve these two problems with a remote monitoring system. The device would measure the three most crucial vital signs for patients suffering from a respiratory disease: respiratory rate, blood oxygen saturation, and body temperature. These values would be taken with adjustable frequency, transmitted to a central database, stored, and displayed on a user interface.

Who will be wearing the device?
The target for the Entremo device are patients suffering from respiratory disease, in more exact terms, hospital patients, who may suffer from Covid-19. It would not be limited to confirmed covid cases, thus minimizing the risk of accidental infection is crucial. In more severe cases it should also be able to monitor bed-bound or unconscious patients, and patients who are assisted in respiration. Therefore, the system would have to be able to take measurements automatically, without any interaction from the patient. Furthermore, it must be ergonomic and comfortable for it to be continuously worn for a few days at a time.

In what environment and by whom will the device be operated?
The primary target sites for our device are non-intensive hospital wards, where patients with respiratory symptoms are treated. This includes wards where patients of the current disease pandemic are treated, which can often be under significant load and operate close to full capacity. At these sites, the nurses would be responsible for handling the devices. This includes putting them on patients, charging, cleaning etc. The monitoring station, where the vital signs of the patients are displayed could be operated by a single person, who could be a nurse or a doctor. The goal is to keep the usability at a level where the operation of the devices and the monitoring station could be handled by anyone after reading a single page of instructions.

Will it be reusable, or does it have to be discarded after a single use?
The goal from the very beginning was to create a reusable, because we found it to be a vastly more efficient use of our resources. The main downside of a reusable device is the risk of cross-infection. Therefore, this problem had to be tackled by making the device disinfectable.

How and where should it be attached to the body?
For our use case, the main factors for deciding where the device would be placed on the body were comfort, ease of use, and the requirements for the sensors. Learning from the head mounted prototype, we have ruled out a glasses-like form factor, however, placing the device on the forehead was still an option. PPG measurements on the forehead are accurate, and it is also a good area for contact body temperature measurements. However, designing an ergonomic form factor would have been challenging, due to the difference in head circumference between people of different ages. Furthermore, it would also be more difficult to fix the device on the head of patients by a nurse, and the unfamiliar nature of the form factor could also reduce the willingness of patients to wear the device. On the other hand, the tried and tested watch-like form factor of a wrist-based device, could also take the same measurements, while also being familiar to patients and straightforward to

use [12]. Therefore, we opted for a wrist-based solution, which would be attached by a strap.

Should it be connected wirelessly, or by a wire?
Having our wrist-based device connected by wire would be very limiting for our use cases. It would require infrastructure at each site that is simply not widely available. Furthermore, patients would need to take off the device each time they leave their hospital bed and may forget to put the device on once they return. It would also lead to confusion in case the patient had to be relocated, or some malfunction arises with the device.

What wireless communications standard to use?
We considered using a direct mobile network connection, however, due to the insufficient coverage of NB-IoT in Hungary, we had to discard the idea. For local wireless networking, we studied three options: Wi-Fi, Bluetooth Low Energy and LoRa. The following table is designated to showcase and compare the protocols, in order to identify the best-suited standard for our use-case.

Table 1: Comparison of wireless protocols

	Wi-Fi	Bluetooth LE	LoRa
Range indoors	Medium, 40-50m	Short, 10-20m	Very long, 5-10km
Power usage	High	Low	Low
Bandwidth	High	Low	Very low
Versatility	Very high	High	Very low
Cost	Low	Low	Medium
Implementation complexity	Low	Low	High

After analyzing the possible wireless communication options, we decided to choose Bluetooth Low Energy, due to its ease of implementation, low cost and high versatility.

What infrastructure is required to operate the monitoring system, and how can it be deployed?
By interviewing staff at multiple hospitals, we have found that patient administration is handled distinctly at different sites. These systems were also closed and highly regulated, thus creating a monitoring system independent of these would be the best solution. Local Area Networks wired

or wireless were not universally available at these sites, and even when they were, their coverage and reliability were unsuitable for a robust monitoring system. However, electricity and mobile internet coverage were universally accessible, therefore we set out to design a system only reliant on these.

To ensure a fast and efficient deployment, we aimed to design a system that only uses wireless and mobile communication and is not reliant on any existing infrastructure. The installation of the system should be as simple as plugging in the monitoring station, the network gateway and the chargers into electrical outlets, and configuring the system on the web-based interface.

How long should it last on a single charge?

To determine the required battery life, we wanted to know how long a patient requiring monitoring spends in a hospital. After discussion with hospital staff, we found out that it can be as long as two weeks, in some cases, even more. By our calculations, we would not have been able to create a reasonably sized device that lasts that long, while also taking measurements frequently. Therefore, we shifted the focus from creating a long battery life, to make the device very quickly and easily chargeable and exchangeable. This way, a 3–4-day battery life would suffice, as the device can be changed for a charged one without losing any data or disturbing the workflow of the hospital staff unnecessarily.

Which materials to use?

For every part of the device that would make contact with the skin, biocompatibility was crucial. The case of the device is made from vapor smoothed polyamide 12, which is not cytotoxic and does not cause skin irritation [31]. The strap is made from a plush material especially sold to be used in contact with the skin. The heat transfer element is made from copper, which does not cause skin irritation and has antibacterial properties. The pulse oximeter is made from a photopolymer resin which is skin and food safe once properly cured.

What would be a typical use process?

The nurse takes the device off the charger, and then the device automatically connects to the closest gateway and appears on the server as available. On the web-based interface, the nurse registers the patient, by filling in their details, then selects the available device from a dropdown list to assign to them. The nurse attaches a strap to the device and then puts it on the wrist of the patient, by fastening the strap using Velcro. The nurse checks that the device is securely attached and is comfortable for the patient. The device automatically starts the measurements, which can be observed using the monitoring station. The interface also shows all previously recorded data for the patient and visualizes them using charts.

The device shows its status using an RGB LED and only requires interaction if the battery is low, or there is some sort of malfunction. The device can be worn continuously throughout the day, except for showering, because it is not waterproof. If the patient moves outside the range of a gateway, the device will try to connect to another one nearby. If there are no gateways within range, the device will store the measurements, and upload the data once it can establish a connection again. When the device is low on battery or monitoring is no longer required for the patient, a nurse will remove the device by unfastening the Velcro. The strap is then removed and discarded, and the device is wiped down thoroughly using disinfectant wipes. The device is then placed on the charger, where it begins charging automatically. Once the battery is full, the status LED as well as the web-based interface shows the staff that the device is ready to be used again. If the patient requires further monitoring, a charged device can be assigned to them on the interface, by selecting it from a list.

3.3 Reaching the final design

3.3.1 Moving to the wrist

Due to the issues mentioned with the head-based prototype, the team decided to move the device to a different region of the body. After researching the feasibility, we have decided to create a wrist-based, watch-like form factor for the monitoring device, as it provides an ergonomic way of measuring all necessary vital signs.

To start the development of the wrist-based form factor, I designed three basic shapes for the body of the device.

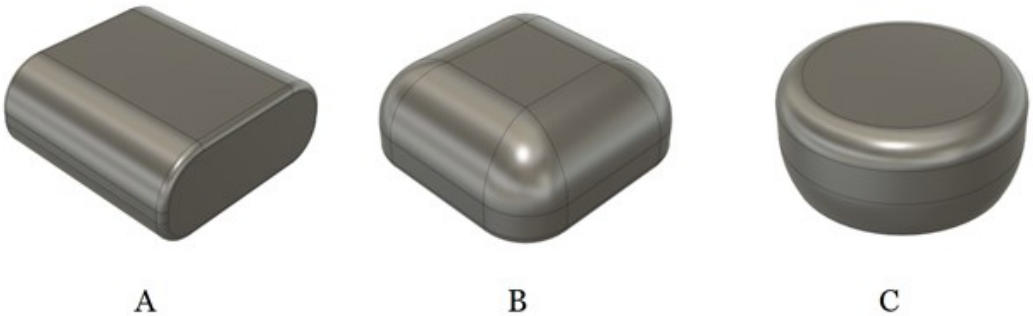

Figure 7: The three proposed device shapes

After discussions with the team, I discarded solution “B”, as it was not aesthetically pleasing and resembled the shape of a certain popular smart watch. I found option “C” limiting in terms of strap attachment and ease of assembly, and the team raised concerns about the difficulty of designing a printed circuit board in a circular shape. This left me with option “A”, which

I found to be a good base for further refinement. It was ergonomic, due to its rounded edges and provided several options for fixing the strap. The team agreed and I proceeded by creating several concept models with different configurations for the strap attachment.

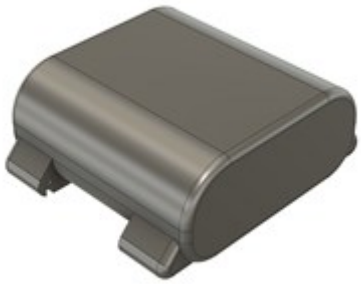

Figure 8: Prototype with the watch strap attachment

The first one used a standard 20mm watch strap that could be attached using spring loaded steel rods. This made it easy to experiment with using off-the-shelf watch straps. The fit was tested with two watch straps made from silicone. 4 of my colleagues and I had worn the prototype with both straps for several hours, and I asked them about their experiences. The conclusion was that while the silicone bands were comfortable to wear for extended periods of time, they were not able to keep the device on the wrist securely enough. This is a major concern, as PPG measurements require secure contact with the skin.

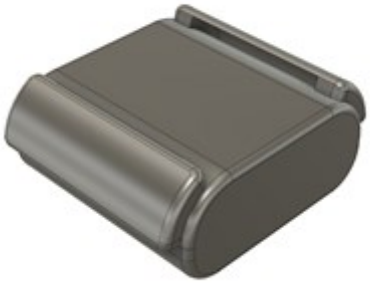

Figure 9: Prototype for textile strip attachment

My next idea was to try to mimic the secure fit of an arm blood pressure monitor, by using a 30mm wide elastic textile strip that could be adjusted and fixed by Velcro.

The textile strap was looped around the device using the two “ears” to keep it attached to the device. The strap was an improvement, as it fixed the device more securely, however the attachment and detachment processes were too complicated.

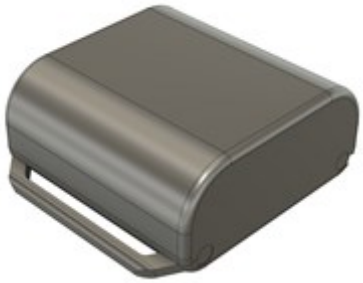

Figure 10: Prototype with strap attachment hooks

As the textile strap was a success, I proceeded to solve the problem of attachment and detachment. I designed this prototype with two removable attachment hooks, which made changing the strap quick and simple and provided a more secure fit on the wrist.

I spent a considerable amount of time designing a mechanism that would allow for quick replacement of these hooks, however, the idea was later discarded in favor of a simpler solution.

3.3.2 Refining the shape and appearance

While the components of the device were in the earlier stage of development, the case of the device could not be accurately designed, due to the lack of information on the internal parts. In this stage of development, I designed an ideal outer shell for the device, which could be later used as a base of development for the working version.

Figure 11: Prototype with attachment hook fixture mechanism

The case had a rounded underside, with a protruding sensor enclosure to better fit the wrist while also providing secure contact with the skin for the sensors.

The design at this stage still featured the removable strap attachment hooks, however, at this stage it was becoming apparent that it would take up too much internal space that would otherwise be used to house the internal components. I used this model to create a version for 3D renders that were used on the company's website as well as other marketing material.

Figure 12: A 3D render of the refined shape

3.4 The final device

The process of designing the final version of the device consisted of numerous experimental prototypes and incremental improvements. However, as there are too many small changes to cover in the scope of the thesis, I will be using the final version to present my solutions and the engineering decisions behind them.

3.4.1 Attachment to the body

At the start of the design process, I had set the following goals for the strap:

- It must be able to provide an ergonomic fit for a wide range of wrist sizes
- It must provide a secure fit to ensure a good skin contact for the sensors
- Putting it on and taking it off must be easy and straightforward
- The strap must be quickly and easily attachable and removable

As a result of testing different polymer and textile-based strap options for the device, I created an optimal solution for our use case. The strap is made from

a 40mm wide elastic plush textile material that is commonly used in the textile industry and is designed to be in contact with the skin. The material is very soft and can be comfortably worn for long periods of time. The elasticity ensures that the device always has secure contact with the skin and provides room for some error when fixing it to the wrist. The width of the strap improves comfort by reducing the pressure on the skin, while also providing more surface area for keeping the device in a fixed position.

The strap can be fastened by strips of Velcro sewn to the main textile strip; however, it is not elastic, thus reducing the overall elasticity of the strap. To combat this, I had placed the Velcro strips intermittently, in a way that keeps the adjustment range wide, while at the same time keeps the strap elastic enough to be ergonomic. Using Velcro makes the device very easy and straightforward to put on and remove, both for the patient wearing the device or by a nurse.

Figure 13: The 3D model and the finished strap

The strap can be attached to the device using two steel buckles, one of them is pre attached to the strap during manufacturing. The device has two hooks where the steel buckle can be snapped in place, one on either side. The strap is attached on one side of the device, looped around the buckle on the other side, and fixed to itself by velcro. This solution ensures the quick and easy attachment and detachment of the strap, while keeping the manufacturing complexity to a minimum.

Figure 14: The 3D model and finished strap attachment

3.4.2 Internals

One of the most important tasks of the case is to house the internal and pass-through components. The device has three main internal parts, the main board, the sensor board, and the battery. My task was to design an enclosure that fixes all components securely and can be assembled and serviced with ease.

My solution is a three-part design, with a main case body and two lids at the ends. One of the benefits of this design is that it can be quickly modified to fit different components while keeping the assembly relatively simple. It can also be prototyped and manufactured quickly and easily. The surfaces joining the parts of the case are also flat and are designed with waterproofing in mind, which is a goal for a future version.

To be able to realize the component fixture, I discussed with the team developing the PCB layout, and requested that they leave a 1mm strip at the edges of the boards that would be used for fixing them in place.

Figure 15: The components of the device case

The main PCB has an RGB status LED on its upper side that needed to be able to illuminate the Entremo logo on the top of the device, therefore its position had to be the uppermost of all internal parts. The magnetic connector, which is soldered to the board, had also had to be seated in the side lid of the case.

The sensor circuit board was designed to be seated flush with the bottom wall of the case, to minimize the distance of the sensors to the skin. To make this possible, the only components on the bottom of the board are the two sensors. The battery was placed between the two boards, fixed securely, while also leaving enough space between it and the boards, in case the battery slightly swells during use.

The main circuit board is fixed by a guide rail that prevents it from moving in the X and Z directions and the two lids prevent it from moving in the Y direction. The lids also have lips to prevent X and Z movement. The hole for the magnetic connector on the front lid also provides additional fastening for the main panel. The sensor circuit board is placed up against the bottom of

the housing. The X movement of the panel is prevented by guide rails and the lids, and the Y and upwards Z are prevented by the lids exclusively. The battery is fixed by guide rails in the X and Z dimensions, while the lids fix in the Y axis.

Figure 16: The internal component fixtures

3.4.3 Pass through components

In this section, I will be presenting the design solutions of the three components that need access to the outside of the case in some way. These are the connector, the PPG sensor enclosure, and the thermal interface of the skin temperature sensor.

Connector
Choosing a suitable physical connection interface for the device was entirely my task. By studying the use cases for our device, I established the following criteria for a connection interface:

- It must be easy to connect and disconnect
- It must be able to carry USB signals
- It should be a non-standard interface to prevent tampering
- It should be waterproof or can be made waterproof

To find a suitable connector, I turned to smartwatches for inspiration, as these devices generally aim to achieve similar goals in their connector design. I had found that most of these connectors used contact target surfaces on the device, and the spring-loaded pins on the connector cable's side. The connection was secured using several methods, including magnets, a clip-like mechanism, or a simple snapping mechanism.

Learning from these existing solutions, I established that I would need to use a spring-loaded connector type, with magnetic fastening. This connector type can easily be disconnected by accident, however, in this case, this is not an issue, as it would mostly be used for charging, and not when the device is in use. On the other hand, a magnetic connection makes connecting the

device with the right polarity very straightforward and easy. It would also make it possible to create a simple charger that can charge several devices simultaneously.

With the properties of the connector established, I set out to find the right one for the device, and soon found the HytePro brand, which manufactures a wide range of connectors and cables. Among their products, there are magnetic, pogo pin-based connectors with 4 leads, perfect for our device. I originally intended to use their waterproof connector, however, that was not available with right angle leads, and the electronics engineering team could not adapt the connector due to lack of time. Therefore, I decided to use their non-waterproof right-angle connector, and the compatible USB cable, the HytePro M512.

Figure 17: The HytePro M512 connector and cable [32]

PPG encapsulation

The main goal when designing the encapsulation of the PGG sensor was to create a barrier that does not absorb the light that the sensor emits, as it would make it unable to operate accurately. Therefore, the material had to be optically transparent at the wavelengths the sensor uses. For this reason, I used a clear 3D printing photopolymer resin, that is also skin safe.

The solution was a 3D printed window that sits between the sensor and the skin of the patient. An important goal was to minimize the thickness of the piece as well as the distance from the sensor, while also providing a secure contact with the skin. Therefore, the thickness of the lower side of the part is only 0.5mm, leaving 0.3mm of space between it and the sensor, and it protrudes 0.2mm from the bottom of the device. The encapsulation is designed to be inserted from the inside of the case and secured using cyanoacrylate glue.

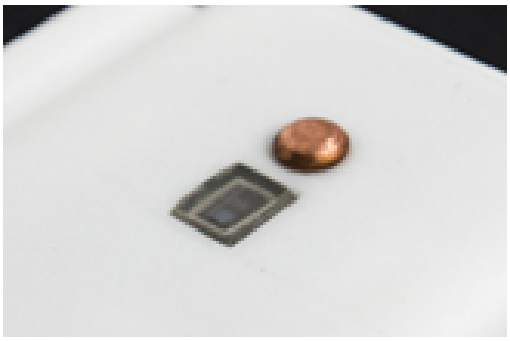

Figure 18: The PPG Encapsulation and thermal interface

To be able to create a part that is uniformly transparent and has a smooth top and bottom surface, I had to print it with these surfaces parallel to the build plate. However, to make this possible I had to design custom surfaces that would not interfere with the part and make post-processing possible without damaging the part.

Figure 19: The PPG Encapsulation part with custom support structure

Thermal interface

The temperature measurements were taken with a contact temperature sensor seated at the bottom of the sensor circuit board. Due to its location, it could not make direct contact with the skin, therefore a heat-conducting interface was required. To meet the requirements outlined in the theory section of the thesis, I designed a heat transfer part that provides good contact with the skin, while keeping the thermal mass of the part to the minimum.

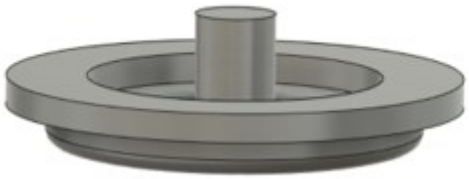

Figure 20: The proposed thermal interface part

Unfortunately, due to time constraints and manufacturing difficulties, I had to come up with a different solution, partly based on off the shelf

components. I chose copper as a material, due to its excellent thermal properties and skin safe nature.

For an appropriate base piece, I had found a copper pin that would be a perfect heat transfer piece with slight modifications. I had cut the top to size and filed the bottom to provide a larger contact surface area and make it more comfortable by reducing how much it protrudes from the bottom of the device.

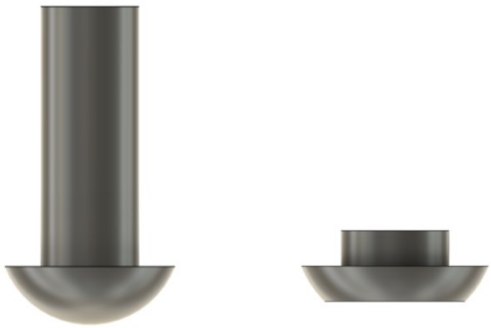

Figure 21: The thermal interface part before and after the modifications

3.4.4 Miscellaneous design solutions

Status LED

The status LED is an integral part of the device, as it is the only form of direct communication it is capable of. The LED was designed to be seated under the Entremo logo on the top of the device, illuminating it when on. To achieve this the light needs to be directed by some means, otherwise, it would illuminate the inside of the device, leaking at the thinnest parts of the case.

To find a solution to this problem, I first designed a dedicated light pipe that would pass through the case, however, this created an uneven surface on the device that would have been difficult to disinfect. I also tried to make the case thinner at the logo and create a light pipe that would be placed under the surface. Unfortunately, the light pipe scattered the light within the case, leading to uneven lighting.

My final solution to this problem consisted of two separate design features. As white sintered polyamide conducts light reasonably well at short distances, I used the case itself as a light diffuser, by designing a protrusion inward just above the LED.

Figure 22: The integrated light diffuser

The integrated light pipe worked reasonably well, however, there was still significant light leakage. To solve this, I designed a shroud that sits between the case and the LED, blocking any light from escaping. This part was printed from a flexible material to conform to the shape of the light diffuser and make assembly possible.

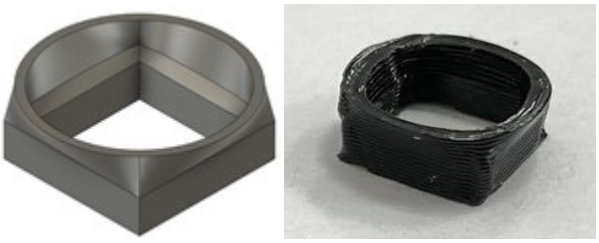

Figure 23: The light blocker piece

Figure 24: The status LED in operation

Sealing
After the case parts were manufactured and I test fitted them, I noticed that due to small variations in the parts, there was a small gap between the main body and the lids on some devices. As I expected this to happen, I already had a solution in mind, which was to 3D print a flexible ring to be placed between the main body and the lids of the case. After several iterations of the design and experimentation with print settings, the 3D seal rings worked adequately.

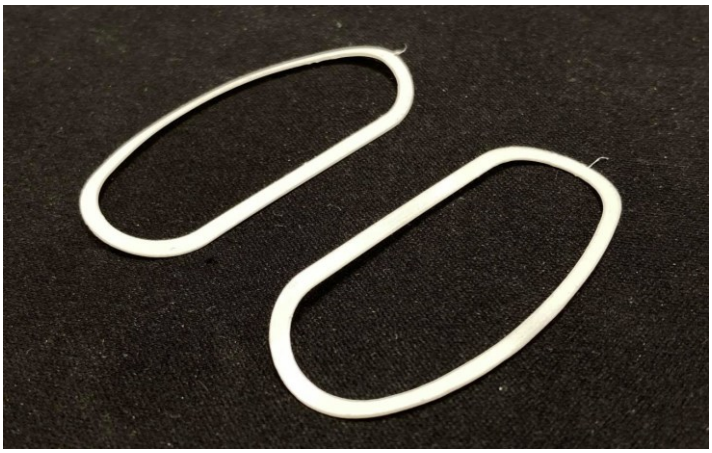

Figure 25: The 3D printed flexible seals

3.5 Device accessories

Besides the device itself, two other pieces of hardware needed to be designed and manufactured. The hubs, the wireless gateways that would transmit the data from the devices, and the chargers, which would be used to charge multiple devices simultaneously. In this section, I will briefly show my solutions and explain some of the design decisions during the process.

3.5.1 The wireless hub

The circuit board for the hub was created by one of the partner companies of Entremo, and it was designed to fit an off the shelf plastic case. However, in the end, it did not fit, therefore I designed a custom case for it. I wanted it to have similar aesthetics to the device, so that it would be instantly recognizable as part of the same system.

Figure 26: The case of the wireless hub

The case consists of two parts, the main body and a lid. The PCB can be slid into a rail in the main body and is held in place by lips on the inside and on the lid. There is a slot for the battery, which can be connected to the PCB before assembly and inserted into the case after the PCB. The battery is also held in place by the lid. To make the case wall mountable, I created cutouts at the back of the device, which make it possible to hang it from two screws. The case is designed with FFF 3D printing in mind, and it needs no support structures. This makes both prototyping and manufacturing quicker and easier.

3.5.2 The charger

To make the charging process more effective, I designed a simple charger that can charge 5 devices at once. The internals are very simple, it consists of 5 magnetic cables connected to a 5V power supply. My solution was to mount the magnetic connectors securely so that the device can simply be placed on top to initiate charging and then it can be disconnected simply by lifting the device from the charger.

Figure 27: The charger

The charge station housing is assembled from 3 3D printed parts using screws to hold them together. All parts are designed for easy printability and assembly. On the right side of the charge station, there is a recessed place where a 3D printed logo can be inserted. The logo part is designed in a way that by simply changing to a different colored plastic filament during the printing process, the colored company logo can be recreated.

Figure 28: The charger assembly

The assembly process of the charge station is the following:
The 5 pre-cut magnetic cables should be inserted into the main part, then the top piece should be secured to it from the bottom using self-tapping screws. Inserting 5 pre-cut magnetic cables from the top of the main part. This is followed by connecting the end of the cables to the power supply and finally, securing the bottom piece with screws.

4 Additive Manufacturing at a Start-up

4.1 Fused Filament Fabrication

4.1.1 FFF Materials

At Entremo, I used a few different materials for our FFF 3D printing needs. By far the most used material was Polylactic acid (PLA), due to its ease of use, fast printability, and low cost. It can be printed at relatively low temperatures and shrinks very little while solidifying. It is also quite tolerant to different printing parameters, making it suitable for smaller, detailed prints, as well as larger, lower resolution parts. The main drawbacks of this filament are its low softening temperature and the impact resistance. Due to its properties, I almost exclusively used PLA for in-house prototyping, where its mechanical properties were not a problem.

PET-G, or polyethylene terephthalate glycol-modified, is a glycol-modified version of PET, a plastic commonly used for manufacturing beverage bottles. Compared to PLA, it has a higher softening temperature and is less brittle, however, it is slightly more difficult to work with. It warps more while cooling, which can lead to deformed undersides when printing larger parts. It also adheres to certain build surfaces with such a force that it can damage the surface when removing the parts from it. Another disadvantage of PETG is its tendency to stick to the nozzle during printing and this built-up molten plastic will then deposit on the printed part, leading to surface defects or print failures in severe cases. PETG was used to print functional, end-use parts, for example, the charging stations and the cases of the Entremo hubs.

Thermoplastic elastomers, or TPE are a class of polymers that are elastic and melt at higher temperatures, making them ideal for printing parts that require flexibility or elasticity. Printing these flexible filaments can be very challenging on certain machines, I had to modify one of our machines to be able to print it reliably. I mostly used TPE to prototype straps and to create seals for the device.

Polyamides, also known as, Nylons are commonly used in SLS printers, however they are also available in filament form for FFF printing. Nylon has excellent mechanical properties, including high impact and heat resistance, therefore, it can be used to manufacture end-use parts. On the other hand, it can be very difficult to print as it requires high print temperatures, warps significantly, and is extremely hygroscopic. Since nylon readily absorbs water from its environment, it must be kept under controlled humidity for storage and printing. The main uses for nylon at Entremo were manufacturing small heat resistant tools, and to experiment with its mechanical properties for the final SLS manufacturing.

4.1.2 FFF Machines

At Entremo, I had access to 4 different FFF 3D printers. Two Creality Ender 3s, a Creality CR-10, and a Craftbot 2.

The Creality Ender 3 is an entry-level hobbyist machine, however, there are many customization and modification options available to improve its ease of use and print quality. With these upgrades, the machine can be a very reliable and affordable option for prototyping. At Entremo, I mostly used them for rapid prototyping and manufacturing when necessary.

The CR-10 is very similar in its properties to an Ender 3, however, it has a larger print area of 300x300x400 millimeters. This made the printer optimal for manufacturing bigger parts, such as the charging stations, or manufacturing a large quantity of smaller parts at the same time.

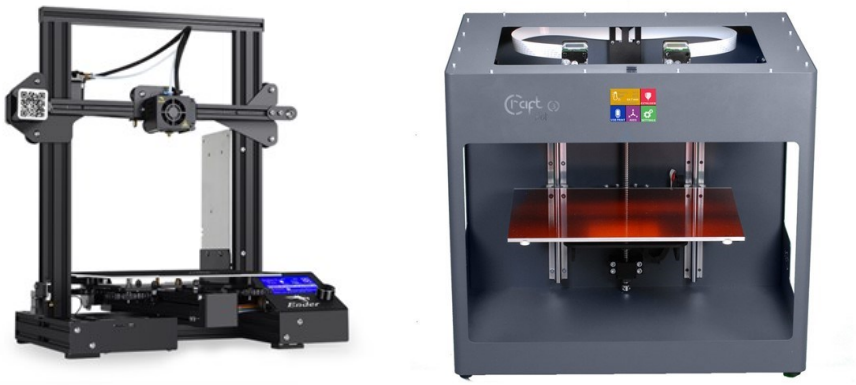

Figure 29: The Creality Ender-3 and the CraftBot 2 3D printers [33], [34]

To make prototyping as efficient as possible, I have fitted all Creality printers with an automatic tramming sensor and a removable flexible magnetic print surface. The sensor ensures that the print head is always an exact distance away from the build platform, by taking measurements of the proximity of the build plate in a grid pattern. The firmware of the printer calculates a Bezier surface using these measurements as control points and uses that to move the printhead horizontally to compensate for the unevenness of the build plate, essentially automatically tramming the machine. After a print has finished, the magnetic build plate makes part removal easier, safer, and faster as it can be easily removed and flexed, which makes the parts separate from the surface.

The CraftBot 2 by Craftunique is a more expensive desktop FFF 3D printer, with rigid construction and high-quality components. This enables higher print speeds, which was very useful at the times when I needed a prototype or a part quickly. The machine is also capable of reaching higher print temperatures, which made it the favorable option to print high

temperature materials, like nylon. For this use case, I modified the printer to have an enclosed build area which helps reduce shrinkage by keeping an even air temperature.

4.1.3 FFF Uses

I used FFF printers both for prototyping and manufacturing purposes. I usually follow the iterative design methodology and iterate on the design of a part multiple times a day. The easy and fast pre and post-processing steps of the FFF process make it an optimal solution for this type of workflow. Having multiple printers provided the ability to try out multiple concepts or solutions at once, saving a lot of time.

The FFF printers were used to print almost all of the prototypes of the device, including concept bodies, experimental component fixtures and mockup components. During the development of the strap of the device, I used the modified Ender 3 to print flexible concepts and prototypes, which mimicked how a final part made from injection molded from silicone would behave. The seals for the small gaps between the components of the device were also printed from flexible filament. I prototyped and manufactured all of the cases for the data transmission hubs and the charging stations. The Entremo logo on the side of the charging stations were also 3D printed using filaments of different colors.

4.1.4 FFF Use process

As with every type of 3D printing, the process starts by exporting the triangle mesh from the CAD software, using the STL file format. The files are then exported into the slicer software of my preference, Simplify 3D. I orient the parts optimizing for quality, easy printability or strength. Then, using a range of settings for quality, speed, layer and material properties, I fine tune the process to suit my need, while I also try to minimize the possibility of a print failure. The slicing algorithm of the software slices the model and creates the GCODE file, which contains the toolpath, print temperatures and other print properties needed for the machine to realize the part.

The printers designated for quick prototyping are connected to a Raspberry Pi, a small development board. This runs a 3D printer controller software called Octoprint, which provides a web-based interface to control the printer, start print jobs over Wi-Fi and monitor the printing process. I use this interface to upload the GCODE file to the Raspberry Pi and start the print. Octoprint then starts sending the lines of GCODE to the printer and provides data on the status of the machine and the print job.

After the print job has started, I visually inspect the first layer of the part, as a good first layer is crucial for a successful print. During printing, I will check on the machine several times depending on the size and complexity of

the part. After the print has finished, I let it cool down to manageable temperatures and remove the part from the build plate. Finally, I remove the support structures if there were any and fix any small defects with a pair of side cutters, and a deburring tool.

4.2 Masked Stereolithography

4.2.1 MSLA Materials

MSLA materials are made from photopolymer resins and their composition is not as clearly defined as with FFF or SLS. Instead of their components, these resins are usually categorized by their material properties.

Standard resin is a category of MSLA materials, which are characterized by their easy printability and low cost. These resins are not meant for mechanically demanding applications, but they can resolve high detail, therefore are most suitable for high-quality visual aids or non-mechanical prototypes. It comes in a variety of different colors and is also available without pigments for optically clear parts. At Entremo, I used standard resin to create concept models and high surface quality prototypes. Clear resin was used to prototype and manufacture the PPG sensor enclosure parts, as optical clarity was crucial for the operation of the sensor.

Tough, durable, or ABS-like resin, is another category of materials used with MSLA printers, focused on mechanical properties, rather than quality. These resins generally cost more than their “standard” counterparts and are harder to print with. They require longer curing times, higher environmental temperatures, and are more prone to warping. The main use for me was printing high detail mechanical prototypes. Besides the materials, I also used resin coloring pigment occasionally, to print prototypes with a certain desired color.

4.2.2 MSLA Machines

I had one MSLA machine at my disposal, which was an Anycubic Photon. It has a build volume of 115 x 65 x 155 mm and an LCD resolution of 2560 x 1440 px. While the machine is quite compact at only 22 x 22 x 40cm, with the Wash & Cure machine and the tools required for post-processing, it takes up a considerable amount of desk space. The machine can easily be controlled by its touch screen, and it can read print files from storage devices plugged into its USB port. The machine is very cost-effective with spare parts and accessories readily available.

Figure 30: The Anycubic Photon and Wash & Cure machines [35], [36]

For finishing the printed parts, I used an Anycubic Wash & Cure machine, which is designed to be used with the Photon printer. As its name suggests, it is capable of both washing the parts in a solvent, and post-curing them using UV light. It has a clamp that can be used to submerge the whole build plate with the printed parts on it in the solvent, which makes post-processing easier and saves time.

4.2.3 MSLA Uses

The most important use for the MSLA printer was to prototype and manufacture the cover for the PPG sensor. This level of detail and optical clarity is very difficult to achieve with other additive manufacturing technologies. One upside of MSLA is the fact that the print time is only determined by the vertical height of the printed parts, therefore, printing multiple parts at once does not add any additional printing time. This was very useful when manufacturing the PPG “windows”, as I could print around 30 pieces in under an hour.

The other main use for the machine was printing prototypes in high detail, which were used to demonstrate how the final version of the device would look to partner companies and the media. Finally, I also printed various mechanical prototypes for the early version of the strap attachment piece. However, due to the time-consuming nature of the post-processing, I tried to use the FFF machines instead whenever possible.

4.2.4 MSLA Use process

The MSLA workflow starts similarly to FFF, by exporting the triangle mesh of the model from the CAD software and importing it into the slicer. The slicer software in this case is ChiTuBox, which is made for use with MSLA machines and has built-in support for the Photon I was using. Orienting

objects for resin printing is different, as the main goal is to minimize the cross sectional area of each layer. This means, however, that the optimal orientation requires a lot of support material to keep the part suspended while printing. Adding support material is a more manual and time-consuming work compared to FFF slicing, partly because of the limitations of the software and partly because of the peculiarities of the MSLA process. There are only a handful of print parameters to choose from, most of these affect the time each layer spends exposed to UV light. The exported file is vastly different from the GCODE used in filament-based 3D printing. Instead of a toolpath, it contains monochrome images which correspond to the masking of the LCD panel. After the file is exported from the slicer, I also run it through an error detection and correction algorithm, using the Photon File Validator software. It can fix most of the errors automatically, and the rest can be fixed manually, by adding or removing pixels to the layers containing the problems.

The fixed print file is transferred to the machine using a USB flash drive, and the print job can be started using the touch screen of the printer. After the first few layers, I pause the print and raise the build platform to confirm that the part is stuck to the build plate.

Safety equipment

After the print is completed, I move the build plate to a 3D printed fixture that holds it above the part and wait for the excess uncured resin to drip from the part. For the post-processing steps I used an Anycubic Wash & Cure machine. In the first step of the post processing, I remove the build plate with the parts still attached and move it to the Wash & Cure machine. I submerge it into a container of isopropyl alcohol and start the wash process. Using a magnetic stirrer, the machine washes the part for a set amount of time, cleaning it from any uncured resin. Once the washing is complete, I remove the build plate and separate the parts from it. I usually remove the support structures from the part at this point using a pair of side cutters. I let the parts dry, put them onto the curing tray of the Wash & Cure machine, and start the UV post-curing program. The machine cures the parts evenly, with the help of a rotating tray and an array of UV LEDs. Once this step is completed, the parts are done, and can be handled without safety equipment.

4.3 Selective Laser Sintering

At Entremo, I did not use any Selective Laser Sintering machines, therefore I do not have any personal experience regarding the process. However, as the final device cases were manufactured using this method, I will briefly explore how SLS works from the point of view of someone using it as a service, and why it was chosen for the task of manufacturing the cases.

While I did not slice the models myself, I had to prepare them to conform to the limitations of the process. This meant I had to make slight modifications to the case, for example, widening the screw holes, to make sure that the machine can resolve it. Some lips and walls on the inside of the case also had to be increased in thickness, to ensure that it would be accurately printed. After I had prepared the model, I sent it to the 3D printing company, and they confirmed that the models are suitable for SLS printing.

The main reasons I chose SLS are its ability to manufacture a larger quantity of cases within a short period of time, and the ability to post-process using vapor smoothing. As the company hired to manufacture the cases also does the vapor smoothing in-house, it made the process for me even easier.

5 Results

To validate the device as a viable medical monitoring solution, two experiments were carried out. In the first test, medical students carried out measurements with the Entremo device and reference devices to compare their accuracy. While I did not take part in this study, I still include it in the thesis as it is an excellent demonstration of the capabilities of the device.
The second experiment was more thorough pilot study at a retirement home, to test the accuracy, usability and reliability of the device. While I did not do the study alone, I did take part in designing, planning and carrying it out.

5.1 Validation with reference measurements

To validate the devices, they were tested against reference measurements from certified medical devices. The goal of the experiment was to investigate the accuracy of the measurements and the performance of the device in general. In the scope of the validation process, 15 patients were involved, and over 50 measurements were taken. The test subjects were between 15-65 years old, included both male and female patients, and they had no know underlying medical conditions.

The test procedure consisted of taking measurements with the medical wearable monitoring device within a one-minute window, and at the same time taking measurements using a finger-based pulse oximeter and an infrared thermometer. After the data has been collected, it was analyzed and the averages for the absolute deviation and relative error were calculated.

Table 2: The test results

Average...	Heart Rate	Oxygen saturation	Temperature	Respiratory rate
… absolute deviation	*2.1702*	*0.8323*	*1.9875*	*2.0625*
… relative error	*2.7969 %*	*0.8483 %*	*5.9303 %*	*13.6377 %*

The average relative error of heart rate and blood oxygen saturation values are below 3%, which is within the requirements of FDA and MDR regulations. However, the skin temperature and respiratory rate readings are not yet accurate enough to meet the requirements and further development is necessary to improve their precision. Moreover, the device occasionally produces invalid results, due to the movement of the wrist. This can happen as reflective blood oxygen saturation measurement requires a very secure and stable contact with the skin, and movement can interfere with the

measurements. This can be solved by using the accelerometer in the device, to only initiate the measurement once the patient is completely still.

While these results are promising, the number of participants and the measurements taken are not great enough to confidently determine the accuracy and reliability of the device. Furthermore, as testing was done only with patients without any serious respiratory symptoms, it is yet to be seen how it performs in its intended hospital setting. In conclusion, these results are satisfactory for this stage of development, however, further testing is necessary.

5.2 Validation at a pilot study

The second validation of the device and the whole system in general was a two-week long pilot study at a retirement home. The goal was to see how the system performs over a longer period, by test subjects, who have never used or seen the device before. While the first study focused mostly on measurement accuracy, this one looked at usability, comfort, reliability as well. There were 7 subjects wearing the device as well as the staff, who managed the monitoring station and handled the devices. During the study, more than 28000 measurements were taken by the Entremo devices, along more than 500 manual reference measurements.

At the beginning of the study, we explained to the participants what the device does, how it works, what its limitations are, and how to use them. We also shown the staff how to use the web-based interface, how to exchange straps and how to charge the devices. The staff was also instructed to carry out measurements with reference devices that we provided three times a day, to be able to compare them to the measurements of the device at the end of the study.

During the study, we periodically visited each participant, and interviewed them about several aspects of the device, such as comfort and usability. We also interviewed the staff operating the devices about the usability of the devices and the monitoring station. At the end of the study, the participants were asked to fill out the questionnaire about their opinion of the device. A final round of interviews was also carried out with the staff.

As the study was just finished, the data is yet to be processed and evaluated, however there are already some preliminary results, mostly from the interviews. The overall feedback from the participants and the staff were very positive, the system worked reliably, and the devices did not cause any major discomfort. The participants also reported feeling safer with their vital signs being monitored and would like to continue using the device once it is on the market. However, there were also some feedbacks on where the device is still somewhat lacking or could be improved. While participants generally found the device to be comfortable, they would have preferred a device that

is smaller in size and weight. Some participants also found the strap attachment buckles too wide, and thus uncomfortable at times. Finally, participants who preferred attaching the device more loosely reported that it had a tendency to move slightly, which could lead to inaccurate measurements.

I would like to conclude this section with a quote from the managing director of the retirement home, Dr. Karolina Horváth:

“Our nursing staff were able to use the Entremo system with ease from the get-go, and the residents were quite assured by the fact that we are looking after them from afar as well. We see the importance of such digital devices, because not only do they allow for more regular, high quality care, but they also reduce the repetitive tasks of nurses, which allow them to dedicate more time to human connections and interactions, ultimately leading to happier residents.”

6 Conclusion

In this thesis, I laid down a theoretical foundation for designing wearable medical monitoring devices, demonstrated the design process, and shown the implementation of the solution. I have also explained the different additive manufacturing processes available for start-ups, compared their capabilities, and shown how they can be used in the development of a wearable device.

The main goal of the thesis was to explore how a wearable medical monitoring device can be designed. The core of the answer can be found in the design goal questions section, which is based on relevant literature, existing solutions, and personal experience. The questions and section answering them give a good overview of the different aspects of designing a medical monitoring system based on a wearable device. Using them as guidelines, future developers of similar systems can gain a deeper understanding of the scope of the challenge, the processes involved, and possible implementations of certain components.

The secondary goal of the thesis was to explore how additive manufacturing can be used at a start-up and in the process of developing wearable devices.

I looked at three different technologies and discussed how they work, their strengths and disadvantages, and how to use them. In the section about the real-world use of the technology, I presented the use cases of the different processes and described their use processes. The contents of this thesis can provide invaluable information for small companies or individuals considering using a certain 3D printing process or investing in a machine themselves. It also points out the certain characteristics of the different technologies that make them suitable for given prototyping or manufacturing needs.

Finally, I presented how the device performed at various tests, including a comprehensive pilot study. These tests confirmed that the system works as intended and stands its ground as a standalone medical monitoring solution. The accuracy of the measurements is acceptable for this stage of development, the device is reasonably comfortable for extended periods of time, and the system works reliably. On the other hand, testing also revealed the most important weaknesses of the device, which will be the basis of further development.

6.1 Future Work

Having learned from the tests and pilot study, the weaknesses and most important potential improvements were identified, and the development of

a new version of the device has already begun. The main improvements are planned involve two parts of the device, the sensors, and the case.

To improve the accuracy and reliability of the heart rate, blood oxygen saturation, and respiratory rate measurements, we have started to develop our own custom PPG sensor package. We are experimenting with different components, layouts, and encapsulations, to find the best solution for wrist-based photoplethysmography. To make the development easier, I designed a testbed with a quickly replaceable component fixture, to be able to try different components and layouts.

Figure 31: The PPG development test bed

The PCB was redesigned to improve the accuracy of the temperature readings, and I am in the process of designing a new thermal interface part with a larger contact area and less thermal mass. The new part will be seated from the inside of the case to improve structural integrity and make waterproofing possible. I will also explore different materials and coatings for the part.

The case of the device will be redesigned to make it smaller and more comfortable on the wrist. The redesign would fit the improved, more compact circuit boards, that are still in the early phase of development. Another goal of the redesign is to make the device waterproof, which is important as it enables additional disinfection methods, and reduces the likelihood of accidental water damage.

While the strap performed well, it could benefit from a non-slip material on its underside, to prevent the movement of the device in case the strap is loosely fastened. Furthermore, its attachment buckle needs to be decreased in width or replaced with a new, custom solution.

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